REMARKS/ARGUMENTS

With this amendment, claims 43 and 46 are pending. Claims 1-42, 44-45, and 47-51 are cancelled without prejudice. For convenience, the Examiner's rejections are addressed in the order presented in an October 27, 2006, Office Action.

I. Status of the claims

Claims 43 and 46 are amended to recite a β1,4-N-acetylgalactosaminyl (GalNAc) transferase polypeptide encoded by a nucleic acid that can be amplified by primers that bind to the 3' and 5' end of the *C. jejuni* LOS locus. Support for β1,4-GalNAc transferase proteins encoded by the *C. jejuni* LOS locus is found throughout the specification, for example, at page 53, line 14 through page 56, line 4. Claim 43 is also amended to recite that the β1,4-GalNAc transferase transfers a GalNAc residue from a donor substrate to an acceptor substrate. Support for β1,4-GalNAc transferase activity is found throughout the specification, for example, at page 20, lines 16-18; page 23, line 12 through page 24, line 16; and page 50, lines 2-14.

II. Priority

According to the Office Action, the priority date of the application is its filing date, April 8, 2004. Applicants have amended the claims to recite a β1,4-N-acetylgalactosaminyl (GalNAc) transferase polypeptide encoded by a nucleic acid that can be amplified by primers that bind to the 3' and 5' end of the *C. jejuni* LOS locus. The present application is a continuation application of U.S. Patent Application No. 10/303,128, filed November 21, 2002, which is a divisional application of U.S. Patent Application No. 09/816,028, filed March 21, 2001, which is a continuation-in-part of U.S. Application No. 09/495,406, filed January 31, 2000, which claims the benefit of U.S. Provisional Application No. 60/118,213, which was filed on February 1, 1999. Support for active β1,4-GalNAc transferase proteins is found in the priority document, the '213 application at page 35, lines 6-8 and SEQ ID NO:6. Thus, in view of the amendment and the disclosures in the related applications, the priority date of the application should be February 1, 1999.

III. Objections to the title

The Office Action objects to the title of the application because it allegedly is not descriptive of the elected invention. In order to expedite prosecution the title is amended to recite β1,4-N-acetylgalactosaminyl (GalNAc) transferase. Therefore, withdrawal of the objection to the title is respectfully requested.

IV. Objections to the abstract

The Office Action objects to the abstract because it allegedly is not descriptive of the elected invention. In order to expedite prosecution the abstract is amended to recite β1,4-N-acetylgalactosaminyl (GalNAc) transferase. Therefore, withdrawal of the objection to the abstract is respectfully requested.

V. Objections to the Information disclosure

The Office Action objects to the form of an Information Disclosure Statement filed with the Application. In order to expedite prosecution, Applicants submit a supplemental Information Disclosure Statement with this response.

VI. Objections to the specification

The first paragraph of the specification is updated to reflect the current status of all priority documents.

The Office Action objects to the presence of hyperlinks in the specification. In order to expedite prosecution, the specification is amended to remove hyperlinks.

VII. Objections to the claims

Claim 51 is objected to for reciting non-elected subject matter. In order to expedite prosecution, claim 51 is cancelled. Withdrawal of the objection to the claim is, therefore, requested.

VIII. Rejections under 35 U.S.C. §101

Claims 49-51 are rejected for alleged lack of utility because they recite β1,4-N-acetylglucosaminyl transferase activity. To the extent the rejection applies to the amended claims, Applicants respectfully traverse. Claims 49-51 are cancelled. Claim 43 is amended to recite a β1,4-N-acetylgalactosaminyl (GalNAc) transferase polypeptide, as is its dependent claim 46. Support for β1,4-N-acetylgalactosaminyl transferase activity is found in the specification at page 20, lines 16-18; page 23, line 12 through page 24, line 16; and page 50, lines 2-14. In view of this amendment, withdrawal of the rejection for alleged lack of utility is respectfully requested.

IX. Rejections for alleged obviousness-type double patenting

Claim 43 is rejected for alleged obviousness-type double patenting over claims 1-3 of US Patent No. 6,210,933 (the '933 patent); claimed 1-7 of US patent No. 6,825,019 (the '019 patent); and claims 1 and 3-5 of US Patent No. 7,078,207 (the '207 patent). To the extent the rejection applies to the amended claims, Applicants respectfully traverse. Claim 43 is amended to recite β1,4-N-acetylgalactosaminyl (GalNAc) transferase polypeptide, rather than glycosyltransferase. The claims of the '933 patent recite α2,3-sialyltransferase activity. The claims of the '019 patent recite β1,3-galactosyltransferase activity. Thus, amended claim 43 is not obvious in view of the '933 and '019 patents.

The '207 patent does recite β1,4-N-GalNAc transferase activity. Applicants stand ready to sign a terminal disclaimer over the '207 patent, in view of the amendment of claim 43.

X. Rejections under 35 U.S.C. §112, second paragraph

Claims 49-51 are rejected for alleged indefiniteness for recitation of "β1,4-N-acetylglucosaminyl (GalNAc) transferase". Claims 49-51 are now cancelled. Claim 43 is amended to recite the correct activity "β1,4-N-acetylgalactosaminyl (GalNAc) transferase." In view of this amendment, withdrawal of the rejection for indefiniteness is respectfully requested.

XI. Rejections under 35 U.S.C. §112, first paragraph, enablement

Claims 43 and 49-51 are rejected under 35 U.S.C. §112, for allegedly failing to provide enablement for any protein with glycosyltransferase or β1,4-N-GalNAc transferase activity encoded by a nucleic acid that can be generated by PCR using primers of SEQ ID NO:40 and 41 using *Campylobacter* genomic DNA as a template. In order to expedite prosecution, claim 43 is amended to recite a polynucleotide sequence that encodes a β1,4-GalNAc transferase polypeptide. The Office Action also alleges that undue experimentation is required to practice the claimed invention. To the extent the rejection applies to the amended claims, Applicants respectfully traverse the rejection.

Factors such as the amount of guidance presented in the specification and the presence of working examples must be considered to determine whether undue experimentation is required to practice the claimed invention. *See, e.g., Ex Parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1985) and *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). As described in *Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Wands*, USPQ2d at 1404, quoting *In re Jackson*, 217 USPQ 804 (Bd. Pat. App. & Int. 1982). Moreover, "[a] patent need not teach, and preferably omits, what is well known in the art." MPEP 2164.01 *citing In re Buchner*, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 221 USPQ 481, 489 (Fed. Cir. 1984).

As set forth in the Manual of Patent Examining Procedure (MPEP) § 2164.01, "the test of enablement is not whether any experimentation is necessary, but whether... it is undue." Further, the "fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation" (citations omitted). Finally, claims reading on inoperative embodiments are enabled if the skilled artisan understands how to avoid inoperative embodiments. *See, e.g., In re Cook and Merigold*, 169 USPQ 299, 301 (C.C.P.A. 1971).

According to the Office Action, "the specification teaches the unpredictability of isolating the desired proteins and that the expectation of success is low." Office Action, at page 9. The Office action also alleges that because the size of the LOS locus is different for different *Campylobacter* species "there is little expectation of success in generating the desired nucleic acid molecules using the recited primers." The Office Action also alleges that "the specification states that the function for any putative glycosyltransferase genes in the LOS of Campylobacter jejuni NCTC11163 (sic) is impossible to predict. . ."

In discussing the function of glycosyltransferase genes of the LOS from *C. jejuni* NCTC 11168 as quoted above, the specification is describing the state of the art before the time of filing. This statement does not include the teachings of the specification. The specification provides the first disclosure of a β1,4-N-GalNAc transferase protein encoded by a nucleic acid from the *C. jejuni* LOS locus. Thus, the specification provides the information necessary to allow those of skill to make and use the claimed β1,4-N-GalNAc transferase proteins. The specification provides the amino acid and nucleic acid sequences of five β1,4-N-GalNAc transferase proteins at, *e.g.*, SEQ ID NOs:16-25. β1,4-N-GalNAc transferase assays are disclosed at, *e.g.*, page 20, lines 16-18; page 23, line 12 through page 24, line 16; and page 50, lines 2-14.

The Office Action also alleges that undue experimentation is required by those of skill to make and use the claimed invention. However, the specification demonstrates that those of skill routinely perform large numbers of glycosyltransferase assays. First, the art at the time of filing and the specification provide methods to efficiently assay thousands of proteins for glycosyltransferase activity. These assays can be scaled up even further. For example, the specification discloses a screening strategy used to clone the nucleic acid encoding the CstI protein, a α2,3 sialyltransferase, from *C. jejuni*. Specification at page 47, lines 11-30 and page 52, lines 16-26. The inventors made an expression library of chromosomal DNA from a *C. jejuni* strain and used to transform *E. coli*. They picked 2600 library colonies and combined them into pools of 100 and then assayed each of the 26 library pools. Thus, the initial screening step required only 26 enzymatic assays to screen 2600 library colonies. Out of 2600 library colonies the inventors were able to quickly identify 2 clones with enzymatic activity. Pooled

assay screens of this type are standard and have been used for many years. Thus, using pooled samples, the number of initial assays can be reduced by 100 or 1000 fold. Similar techniques can easily be used by those of skill to identify functional β1,4-GalNAc transferase proteins. Thus, undue experimentation is not required to practice the claimed invention.

In view of the above amendments and arguments, withdrawal of the rejection for alleged lack of enablement is respectfully requested.

XII Rejections under 35 U.S.C. §112, first paragraph, written description

Claims 43 is rejected under 35 U.S.C. §112, for allegedly containing subject matter that was not described in the specification as filed. The Office Action alleges that those of skill would not recognize that the inventors had possession of the claimed genus at the time of filing.

Applicants respectfully traverse the rejection. As currently applied, the specification does comply with US patent law for description of a nucleic acid or amino acid sequence. The Federal Circuit court of Appeals addressed the description adequate to show one of skill that the inventors were in possession of a claimed genus at the time of filing. *See, e.g., Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 63 USPQ2d 1609 (Fed. Cir. 2002). An applicant may also show that an invention is complete by

> . . . disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention . . . *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. *Id.* at 1613.

Furthermore, "description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces." *See, e.g.*, 66 Fed. Reg. 1099, 1106 (2001).

The specification does provide descriptive support for the full scope of the claimed genus by providing a representative number of species of β1,4-GalNAc transferase amino acid sequences and encoding nucleic acid sequences, *e.g.*, SEQ ID NOs:16-25, and a β1,4-

GalNAc transferase assay used to determine whether polypeptides have the enzymatic activity required by the claims. The assay is described at page 20, lines 16-18; page 23, line 12 through page 24, line 16; and page 50, lines 2-14. This information is more than adequate to meet the written description requirement, particularly in view of *Enzo*, cited above, recent Board decisions, and the interpretation of the Written Description Guidelines evidenced by the USPTO's own Synopsis of Application of Written Description Guidelines.

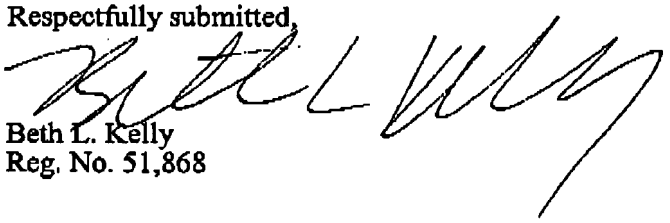
In view of the above arguments and amendments, withdrawal of the rejection for alleged lack of written description is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



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